Canadian Centre for Mine Action Technologies
Le Centre canadien des technologies de déminage

Queen's UNIVERSITY

11375-1 (DSTL 4)

November 2001

Distribution List

TRIP REPORT CLINICAL ASSESSMENT OF THE NIAGARA FOOT ARANYA PRATHET THAILAND 1-10 NOVEMBER 2001

References: A. Niagara Foot Project Review Meeting, 10 Aug 01.
B. CCMAT Management Committee Meeting, 01 October 2001.
C. DGRDC Approval, dated 5 October 2001.

1. As directed by the CCMAT management committee at reference B, CCMAT representatives with Niagara Prosthetics and Orthotics (NPO) and Queens University visited the Thailand Mine Action Center (TMAC) between 01 - 10 November 2001. The aim of the visit was to:

a. Negotiate and sign a letter of concurrence between TMAC and CCMAT that would allow for a long-term (one-year) evaluation of the Niagara Foot in Thailand.

b. Conduct a pilot study of the Niagara Foot with 20 mine victims who volunteered to provide feedback on the performance of the foot.

c. Establish contact between Queens University in Kingston Ontario and Chiang Mai University in Chiang Mai Thailand to set up an academic exchange between Thailand and Canada.

Figure 1: Test Site Location

2. **LETTER OF CONCURRANCE (LOC).** A letter of concurrence was negotiated and signed on behalf of the Director General Defence Research Establishment Suffield and Lt Gen Gitti TMAC's Director General. The LOC is self-explanatory and is attached as Annex A to this report. This LOC establishes the context and responsibilities for conducting and reporting on a one-year clinical evaluation of the NPO Foot in Thailand. While no specific timeframe is included in the LOC the project team put in place the framework of the long-term study during this trip. The long-term evaluation of the Niagara Foot has started. Doing a clinical evaluation in Thailand provides the project team with an independent evaluation of the Niagara Foot™ and ensures that the evaluation would be done in the right environment thus providing a realistic assessment of the foot.

3. **Site location.** The clinic where the study is being conducted is located in the city of Aranya Prathet, Sa Kaeo province, 350 kilometers East of Bangkok on the Thailand/Cambodian border. This area was militarily active as early as 5 years ago and is infested with landmines and unexploded ordnance. In its early years Handicap International set up the Aranya clinic and it was one of several clinics located in the area. In its early years Aranya clinic serviced about 800 mine victims per year. Today hostilities have ceased but the mine and UXO threat remains. The staff operating the clinic is experienced at making and fitting prosthetics using a system of custom made sockets and modular components provided by Handicap International.

Figure 2: Aranya Prathet Hospital

4. **Pilot Study Results**. The combined NPO and Queens University team went to Arnaya prepared to conduct a three-day pilot study of the foot. The pilot study goals were to:

a. Confirm the technical content of the questionnaire that would be used in the long-term study;

b. Put the Niagara Foot on 20 patients to hear their initial feedback; and

c. Establish a link between Queens University and Chiang Mai University to facilitate an academic exchange.

Figure 3: Prosthesis Workshop

5. Queens University developed two questionnaires that were used to establish the technical content of a long-term report on the fit, form and function of the Niagara Foot. The first questionnaire was a Patient Questionnaire, which gave the team the opportunity to evaluate the Niagara Foot with the patients existing foot (Annex B - Patient Questionnaire). Getting immediate feedback from people wearing the Niagara Foot provided a significant amount of information to the team after the first three days of the pilot study. It was found that the Queens University Patient Questionnaire is an appropriate tool for acquiring data on the Niagara Foot performance and will form the basis of the questionnaire that will be used in the long-term study. The questionnaire will be put in a "post card" format that can be filled out by the clinic and patient and mailed directly to Queens University. The second questionnaire dealt with the Physiological Data (Annex C - Physiological Data) that could be collected if a more academic study were to be pursued.

Figure 5: Interview Process

6. A pilot study was performed under a protocol approved by Queen's Universtiy Human Ethics Review Board. Initially 20 mine victim volunteers were recruited to participate in the pilot study. During the preliminary briefing to the patients it was made clear that they could opt out of the evaluation at any time and that it would in no way jeopardize any future service they may require from the clinic. Out of these 20 people, five people did not participate because they changed their mind or their existing prosthetic devices were so incompatible with the Niagara Foot that they could not continue with the trial. Of the 15 people that did continue 8 provided feedback at the end of the third day. The 8 people that returned to the clinic on the third day had the opportunity to wear the foot for one full working day before returning to the clinic to fill out a patient questionnaire. Initial feedback indicated that by wearing the foot people are less tired at the end of the day. People could walk faster with the Niagara Foot than compared to their old foot, and they could operate machinery easier. This positive feedback provides enough information to encourage the project team to keep investing in the foot and develop it into a final product. Queens University will write a technical report that provides an in depth analysis of the data already assembled as a result of this three-day pilot study.

7. At the end of the pilot study all 15 people that participated elected to continue using the Niagara Foot. Many returned on the last day to have their prosthetic devices permanently altered so that they could gain the maximum benefit from wearing the Niagara Foot. On the last day two people had new limbs made from scratch. The need to make completely new limbs was driven by two user needs. Some users had limbs made with wooden cores. These limbs were so saturated from working in wet fields that water poured from them when the prosthesist tried to fit the Niagara Foot. Because the limbs were wet for an extended duration the wooden core was rotten and needed to be replaced or repaired. Repairs were achieved using a field-designed coupling that was manufactured in local machine shop whle the pilot study was in progress. In some cases the clinic made new limbs. The new limbs consisted of both modular and custom made components and were the first purpose built limbs for the Niagara Foot. The second need for new limbs was that some people had a need for a working foot and a "good" foot that could be worn around town and to the temple. In those cases the user elected to use the Niagara Foot as the "good" foot and a completely new limb was built. Two mine victims elected to use a Niagara Foot, without a cover, in the fields as a working foot. Feedback will be required to see if there are any durability issues related to the heavy use of the foot in this environment.

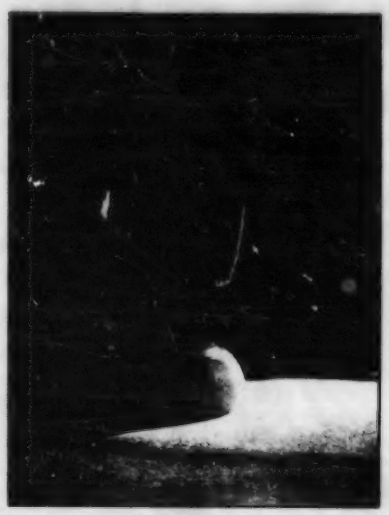

Figure 6: Purpose Built Limb

8. **Action items**.

a. **CCMAT**. The long-term study of the Niagara Foot will require user input and feed back from the clinic at the Arnaya Prathet Hospital. It is planed that patients return to the Arnaya clinic at four different times between December 2001 and November 2002. In order to achieve this the Aranya Prathet clinic requires a small operating budget of $936.42 CAD (26,000 THB). Giving the clinic an operating budget allows the director to provide the volunteer's an allowance that offsets the cost that they incur by travelling to and from the clinic to participate in the study. It also pays for shipping and handling of reports and returns and provides an allowance for the clinic's prosthesits to monitor the Niagara Foot and fill out the reporting forms. The clinic will

set up a specific account at the Aranya Prathet Thai Farmers Bank, the CCMAT can transfer funds into the account via the Canadian Embassy Bangkok. Annex D - Long Term Study Budget, for a detailed cost estimate.

b. **Niagara Prosthetics and Orthotics.**

(1) **Feeback Forms**. NPO, with Queens University, will provide the Aranya Clinic with a questionnaire written on a self addressed and stamped "post card" in order to get feedback on the performance and durability of the foot.

(2) **Redesign**. During the pilot study the most common patient comment about the foot is that it needs to be made to look more like a foot (the heel is too wide). The foot also needs to come in more sizes. NPO with Queens is to look into narrowing the heel and then making the foot in appropriate sizes for the region as a step towards the final design.

(3) **Follow Up Visit**. It is anticipated that a follow up visit made up of CCMAT, Queens University, and NPO be made in May 02 to observe the durability and monitor the performance of the foot first hand. This would be a CCMAT funded activity.

Figure 3: Redesign of Heel

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Canadian Center for Mine Action Technologies

Dr. T. Bryant
Queens University

Annex A- Letter of Concurrence (LOC)
Annex B - Patient Questionnaire
Annex C - Physiological Data
Annex D - Long Term Study Budget
Annex E - Contact List

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Canadian Centre for Mine Action Technologies
Le Centre canadien des technologies de déminage

11375-1 (DSTL 4)

October 2001

PROJECT CONCURRANCE BETWEEN THE CANADIAN CENTER FOR MINE ACTION TECHNOLOGIES AND THE THAILAND MINE ACTION CENTER UNDER THE PATRONAGE TO HER ROYAL HIGHNESS PRINCESS GALAYANIWATTANA KROMLUANGNARATIWAT RATCHANAKARINDRA FOR THE CLINICAL EVALUATION OF THE NIAGARA FOOT ™ IN THAILAND

References: A. Queens University Engineering Report. (attached)
B. Logistics Support Plan, dated September 2001. (attached)

BACKGROUND

1. In August 1998 the Government of Canada formed the Canadian Center for Mine Action Technologies (CCMAT) as part of its Mine Action Initiative. The purpose of the CCMAT is to develop new technologies for humanitarian demining. With the support of the CCMAT and the National Research Council of Canada, a Canadian company called Niagara Prosthetics and Orthotics developed a new prosthetic foot (Niagara Foot ™) to aid victim assistance efforts in mine affected areas. What sets the Niagara Foot ™ apart from other similar devices is that it provides flexibility through the entire action of planting the foot, transferring the weight forward and at toe off. Another defining quality of the foot is the durability of the design. Most prosthetic feet are susceptible to damage by water, fatigue and fail before 200,000 cycles. Testing to date has shown the foot meets or exceeds the 1-million cycle requirement as laid down in ISO. A final step in the development process is to conduct a peer review of the Niagara Foot ™ in a prosthetics clinic.

PURPOSE

2. This letter details the concurrence of the Director of the Canadian Center for Mine Action Technologies and the Director of the Thailand Mine Action Center (TMAC) under the patronage to Her Royal Highness Princess Galayaniwattana Kromulangnaratiwat Ratchanakarindra to clinically evaluate the Niagara Foot in Thailand and the responsibilities of each party to ensure the successful clinical evaluation of the foot.

3. Once signed by authorized representatives of each party this agreement becomes the foundation for the Logistics Support Requirements Plan (LRSP) attached as annex A to this letter. This agreement and the final LSRP may be amended upon mutual consent of all signatory parties. Amendments shall be made in writing and signed by all parties.

RESPONSIBILITIES:

4. The TMAC agrees to provide the following support IAW the Logistics Support Requirements Plan attached to this agreement:

a. Provide a letter of exemption to ensure timely customs clearance of NPO tools and 20 Niagara feet through the TMAC chain of command, Ministry of Defense, to the Thailand Foreign Ministry/Privilege section.

b. Brief the CCMAT team on the structure of Victim Assistance in Thailand.

c. Coordinate the support of National and Provincial level organizations working in Victim Assistance in Thailand as well as the clinic where the trials would take place.

d. Monitor and facilitate reporting of the clinical trial results.

e. Facilitate the CCMAT/NPO field team to:

(1) Instruct the clinic staff how to use the Niagara Foot ™ and assess its performance.

(2) Fit 20 Niagara feet; and

(3) Take 20 below knee amputee castings.

f. Assist the CCMAT/NPO Field team by arranging local accommodations.

g. Provide the CCMAT/NPO Field team with local security if required.

5. CCMAT agrees to provide the following support IAW the Logistics Support Requirements Plan and this agreement.

a. Provide the trial objectives and criterion that would be monitored by the clinic evaluating the foot.

b. Provide the tools and materials to fit 20 Niagara Feet, with outer covering for the purposes of the trial.

c. Provide the material for casting 20 below knee amputations.

d. Provide transportation for the CCMAT/NPO field team.

e. Arrange/coordinate the customs clearances required for importing the tools Niagara Feet into Thailand. Liaison with Canadian Embassy personnel for gaining assistance in establishing customs clearance with the Thailand Foreign Ministry.

f. Coordinate and publish the results, with TMAC and the clinic in Thailand.

6. **Issue**:

a. This assessment is dependent on the ability of TMAC to arrange trained P&O professionals and clinical support as well as 20 below knee amputee volunteers to implement the clinical trial.

b. Should this evaluation prove to be successful the Government of Canada, through the Department of Foreign Affaires and International Trade may consider support to TMAC for victim assistance in Thailand based on the Niagara Foot ™ and other products developed under the CCMAT.

7. This concurrence between TMAC and CCMAT involving the Joint Clinical Evaluation of the Niagara Foot is an organization to organization concurrence not legally binding to the Royal Thai Government.

8. Signatures:

FOR CANADIAN CENTER MINE ACTION TECHNOLOGIES

_____
Dated:

FOR THAILAND MINE ACTION CENTER UNDER THE PATRONAGE TO HER ROYAL HIGHNESS PRINCESS GALAYANIWATTANA KROMLUANGNARATIWAT RATCHANAKARINDRA

_____
Dated:

List of Annexes

Annex A	Logistics Support Plan
Annex B	Draft Trial Objectives and Criterion
Annex C	NPO Fatigue Tester Final Report 2001
Annex D	Block Visit Plan November 2001

Date_____

Subject Questionnaire

Name_____ Subject Code_____

Height_____

Weight_____

Leg Amputated Left ☐ Right ☐

Cause of Amputation_____

Type of Prosthetic(s) currently used [please list in order of most used – least]

1 _____

2 _____

3 _____

4 _____

Activity Level

Sedentary ☐

Somewhat active ☐

Active ☐

Very Active ☐

Athletic ☐

Elite Athlete ☐

Fields Tests for the Evaluation of the NPO Foot

The following tests were reported by Olney et al. in 1979 to establish objective measures of gait performance in clinically important areas of 1) fundamental skill; 2) characteristics of free walking; 3) effort of walking; and 4) walking endurance. It has been modified slightly to include measures to record the Physiological Cost Index (PCI) reported by Rose et al. 1991.

Equipment:

- minimum 15 meter measuring tape
- masking tape
- a stop watch
- 4 meter parallel bars - Height ?
- a measured distance of 15 meters
- five stairs with a rise between 13 and 17.5 cm
- A heart rate monitor would simplify recordings

Description of Test Items:

#	Test	Description
1a	Resting Pulse	The test is not administered within an hour of eating, drinking coffee or smoking. If medication could have affected heart rate, the medication name is noted under "Comments" on the recording sheet. The subject rests quietly for 10 minutes before a 20-second pulse count is taken.
1b	Effort of Walking	Heart rate is recorded at rest and after two minutes and six minutes of walking. Subjects are instructed to walk as fast as possible safely for 6 minutes. The distance walked in meters and the heart rate at the 2 and 6 minute marks is recorded.
2	Total Distance	The patient walks until he begins to feel tired or uncomfortable, or until 15 minutes has elapsed. The total distance is recorded.
3	Bilateral Stance	The subject stands upright in the parallel bars bearing weight on both limbs for as long as he can or until 30 seconds has elapsed. No hand support is used.
4	Uninvolved Limb Stance	Weight is borne on the uninvolved limb while lifting the opposite leg for as long as possible or until 10 seconds has elapsed. If necessary, the subject is permitted to steady himself lightly with one or both hands on the bar, although no weight-bearing through the hands is permitted.

LONG TERM STUDY
BUDGET

1. The CCMAT with a team from Queens University and Niagara Prosthetics and Orthotics conducted a pilot study of the Niagara Foot in Arnaya Prathet Thailand, 1-10 November 2001. During the pilot study it was established that an allowance might be paid to the patients and workers participating in the study. It should be made clear that the purpose of the allowance is not to contract for peoples services. Contracting for peoples services could skew the test results by purchasing peoples input. Instead the allowance pays for reasonable costs people incurred by participating in the study such as travel to and from the clinic, food and water while they wait, and finally some compensation for the time they take off work.

2. The following estimate was coordinated with the director of the Aranya Prathet hospital on 8 November 2001. The Hospital Director has oversight of the prosthetic clinic located on the hospital grounds. It is proposed that CCMAT would provide the entire budget in a one-time cash transfer into an account that is managed by the Aranya Prathet hospital.

3. In the pilot study the 15 volunteers elected to keep the foot and wear it for the duration of the long-term study. It is proposed that the volunteers would return to the clinic after one month, three months, six months and one year to provide feedback on the performance of the Niagara Foot.

Item	Description	Cost Per visit	Comment
1	Volunteer Allowance 200 THB per person x 15 People	3000 THB	Covers travel and food
2	Clinic Workers Allowance 200 THB per person x 2 Workers	400 THB	Covers interview time and filling out the Queens Performa
3	Photocopying	100 THB	
4	Equipment and Repairs	1000 THB	To cover repair and replacement of worn parts
5	Shipping and Handling 1000 THB per shipment x 4	4000 THB	To cover shipping worn or broken feet back to Canada
6	Subtotal Per visit	6500 THB	$234.10 CAD
Project Total (four visits)		**26,000 THB**	**$936.42 CAD**

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5	Involved Limb Stance	Weight is borne on the involved limb lifting the opposite leg for as long as possible or until 10 seconds has elapsed. The subject is allowed to steady himself, as for item 3.
6	Dynamic Weight Transfer	Following a demonstration, the subject performs ten steps in place as rapidly as possible. The subject stands in the parallel bars and holds onto them. The first few steps are used as a warm-up and a count of zero at foot down begins the timing. The time for 10 full steps of the same foot is recorded.
7	Speeded Ambulation in Parallel Bars	The subject walks through the parallel bars, as quickly as possible using hand support. Timing starts as soon as the subject passes the uprights of the parallel bars and ends when he reaches the four-metre mark. A second trial is taken as the subject walks in the opposite direction.
8	Speeded Ambulation with Walking Aids	The subject walks as quickly as possible with his usual walking aids for four meters outside the parallel bars. The time for two trails is recorded.
9	Stair Ascent	The subject is directed to ascend five stairs at his normal speed. He uses handrails or assistive devices, and the type of aid is recorded. The stair rise must be between 13 cm and 17.5 cm high. Timing begins as soon as the subject lifts his foot in preparation for a step and ends the instant the second foot contacts the fifth stair. The time for two trials is recorded.
10	Free Cadence Walking	A straight away lap distance of 15 metres is selected and marked. The subject is asked to walk at the speed that best suited him with his usual aids. The stop watch is started when the subject's right heel contacts the starting line. The number of strides the subject takes during one lap, to the nearest quarter stride, (1 stride = from heel contact of one foot to next heel contact of same foot) is recorded.

References:

Olney SJ, Elkin ND, Lowe PJ and Symington DC. (1979) An ambulation profile for clinical gait evaluation. Physiotherapy Canada, 31(2):85-90.

Rose J, Gamble JR, Lee J, Lee R, Haskell WL. (1991) The energy expenditure index: A method to quantitate and compare walking energy expenditure for children and adolescents. Journal of Pediatric Orthopaedics 11:571-8.

NPO Field Trial Data Sheet

Subject Code: _____
Visit Date (dd/mm/yy): _____ Visit Number: 1 2

Subject status:

General Health 1- poor 2 - fair 3- good 4- very good 5- excellent
Right Foot _____
Left Foot _____
Weight (kgs): _____
Height (cm): _____
Age (yrs): _____
Sex: M F
Foot tested: R L
Prosthetic Foot: NPO other specify: _____
Accommodation - days adjusting to current prosthetic: _____

Test Measurements:

1a-Resting Heart Rate (beat/20 s): _____

1b-Effort of Walking
2 minutes (beat/20 s) HR: _____ Distance: _____
6 minutes (beat/20 s) HR: _____ Distance: _____

2-Total Distance (m): _____ 15 min or less

3-Bilateral Stance (s): _____ 30 s max

4-Uninvolved Limb Stance (s): _____ 10 s max

5-Involved Limb Stance (s): _____ 10 s max

6-Dynamic Weight Transfer (s): _____ 10 steps

7-Speeded Ambulation in Parallel Bars (s): _____/_____ 2 trials

8-Speeded Ambulation with Walking Aids (s): _____/_____ 2 trials

9-Stair Ascent (s): _____/_____ 2 trials - 5 stairs

10-Free Cadence Walking (15 m) Time: _____ # Strides: _____

Comments on testing:

Medication: _____

Aids used: Speeded walking (#8): _____ Stair ascent (#9): _____

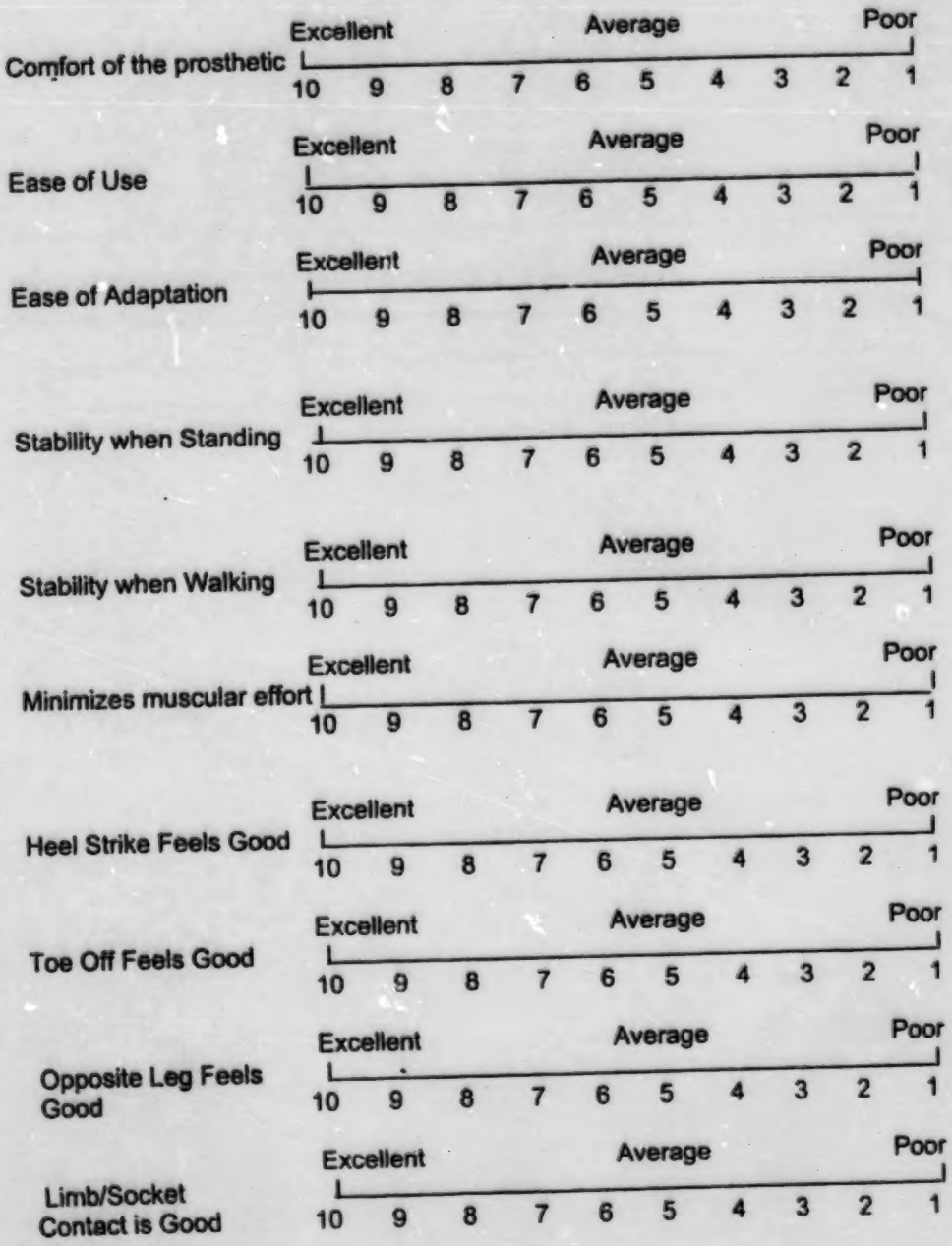
_____

_____

_____

_____

Evaluation of Prosthetic SACH ☐ NPO ☐



Do you feel you could use this foot to walk on for an entire day Y ☐ N ☐

Comments:_____
_____
_____
_____
_____
_____